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DRAWINGS ATTACHED

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## (54) SURGICAL DILATOR


(71) We, NATIONAL RESEARCH DEVELOPMENT CORPORATION, a British Corporation established by Statute, of P.O. Box 236, Kingsgate House, 66—74, Victoria Street, London, S.W.1, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—


This invention relates to surgical dilators and in particular to an oesophageal dilator.

According to the invention, there is provided a surgical dilator comprising a hollow tubular member, the wall of which is provided by a tubular metal core of lattice form and a continuous layer of a resilient material, the elements making up the lattice defining diamond shapes in the unstressed condition of the dilator, the major diagonal dimension of each of which shape being in the direction of the longitudinal axis of the wall and the included acute angle of each shape in the unstressed condition of the dilator being between 45° and 60°, the dilator being such that when the dilator is subjected to an axial tensile force, the wall will be caused to contract diametrically and extend axially and will return substantially to its normal shape of its own accord when the force is removed.

Features and advantages of the invention will be apparent from the following description of embodiments thereof given by way of example only in conjunction with the accompanying drawings in which:—

Figures 1 to 3 show diagrammatically different embodiments of dilator, the resilient layer in which the dilator core is embedded being deleted for the sake of clarity; Figures 2 and 3 being partial views of the core;

Figure 4 is a transverse cross-section of the dilator of Figure 1, with the addition of spikes;

Figure 5 shows diagrammatically a pair of tensioning forceps for inserting the dilator into an oesophagus in conjunction with an oesophagascope;

Figure 6 shows diagrammatically an instrument for inserting the dilator into an oesophagus, and

Figure 7 shows in cross-section a sleeve covering a dilator according to the invention.

Referring to Figure 1, the dilator comprises a hollow tubular member the wall of which is defined by a tubular core 1 of lattice form embedded in a continuous tubular layer 3 (Figure 4) of a resilient material such as rubber. The elements 2 making up the lattice are of metal, for example, stainless steel wire, and define diamond shapes the major diagonal dimension of which being in the direction of the longitudinal axis of the dilator wall. The included acute angle $\alpha$ of each diamond formed by the elements in the unstressed condition of the dilator is between 45° and 60° since this range gives the desired low values for the ratio of axial extension-to-change in diameter of the dilator. Low values for this ratio are required when the dilator is to be used in an oesophagus since only small axial extensions of the dilator can be tolerated. The elements may be woven or plaited.

To enable the dilator A to be inserted in, for example, the oesophagus, loops 4 (Figure 5) are formed at each end of the core 1 to enable, as will be apparent later in the description, a tensioning instrument to apply an axial tension force to the dilator to contract it diametrically and to extend it axially; these loops are rubber coated and may be provided by the ends of the core 1 or may be separate loop members secured to the core. Care must be taken to ensure that the loops have no tendency to bend inwardly of the core where they will foul the lumen of the dilator.

The tensile strength and diameter of the wire, the number of wires used and size of the weave together with the resilience of the layer will determine the physical characteristics of the dilator. By selecting these factors a variety of useful dilators can be produced of different sizes, varying in length and diameter.

The ends of the metal wire of the core

may be joined by swaging or welding to give a rigid or springy end or if the ends are formed without joining, that is to say if the core 1 is made from a single wire, then the mouths 1a (Figure 5) of the dilator will take on a desirable divergent shape.

In an alternative form, see Figure 2, the core 1 is formed from metal wires 2 which are not woven or plaited but which are crimped together to form the lattice structure, the structure then being embedded in a layer of resilient material.

In a further alternative (not shown) the core 1 is made from two helical metal springs, one within the other and wound in the opposite direction to form a lattice structure, the structure again being embedded in a layer of resilient material (not shown).

Referring to Figure 3, the core 1 is produced from hinged metal slats 2, for example of stainless steel, which are tensioned by springs 2a to tend to expand the dilator diametrically and which again are embedded in a continuous layer of resilient material.

To insert the above described dilators into, for example, the oesophagus of a patient, a pair of tensioning forceps 5 are employed (see Figure 5) in conjunction with a standard oesophagoscope (not shown). The forceps 5 have hook-like projections 6 for hooking into corresponding loops 4 at both ends of the dilator A and relatively slidable shafts 7 for applying an axial force to the dilator when hooked on projections 6, to extend it axially. In the extended condition, the dilator can be passed through the oesophagoscope into the oesophagus; when the forceps are released from the dilator, the dilator will tend to return to its unstressed shape and will therefore press outwardly against the wall of the oesophagus. The forceps and oesophagoscope can then be withdrawn from the oesophagus.

In another method of dilator insertion, an instrument 10 (see Figure 6) is employed in combination with the above described dilators. This instrument differs from the normal form of oesophagoscope in that it includes a dilator portion 15 (similar to the dilators described above) attached by one end to the distal end of the oesophagoscope 12 and axially extendable or contractable by a manually operable control 11. To insert one of the dilators described above and separate from dilator portion 15, the instrument is introduced into the oesophagus with an internal obturator 13. The obturator is then withdrawn, and the separate dilator is lubricated and introduced into the proximal wide end of the instrument and pushed down to the distal end which, being much narrower forces the separate dilator into its long thin extended shape. The separate dilator is then extruded at the desired level through dilator portion 15 while the instrument is withdrawn, separation of the instrument from the separate dilator being facilitated by suitable manipulation of the shape of dilator portion 15 by control 11. In the removal of the separate dilator, the instrument is re-introduced, and its dilator portion 15 is opened out by control 11 and gradually insinuated round the end of the separate dilator in the oesophagus, to enable it to be drawn into the end of the instrument, after which it can be grasped with a pair of forceps 5, drawn into its extended position and withdrawn together with instrument 10.

In a further method of insertion, see Figure 7, the dilator A prior to insertion is encased in a constricting cylindrical cover B, such as of plastics material, so that it is retained in its extended axial position. An obturator is then introduced into the dilator to engage its distal end and the obturator and dilator are then inserted into the oesophagus whereupon the cover B is pulled off, permitting the dilator A to expand diametrically, and the obturator is withdrawn.

Uses of the above described dilators in the oesophagus are as follows.

1. Dilatation.

(I) For malignant strictures:

Here it is used as a terminal measure in inoperable carcinoma, to enable the patient to swallow better, owing to the fact that it offers a wider lumen than the Porges, Mouseau Babin or Celestin tube, and is constantly dilating. There is less tendency for blockage to occur and the patient may be able to swallow more naturally, with less dependence on a liquid or sloppy diet. Owing to the tendency to press outwards, together with the divergent ends, there is less tendency for it to slide down the oesophagus. The dilator used in this connection may have more of the resilient layer cut away from the wire framework at the ends, to allow better adhesion to the wall of the oesophagus.

It might be convenient also as a means of delivering a measured dose of radio activity to some part of the oesophagus.

(II) For benign strictures including

1. Post-traumatic—following (a) surgical operations or anastemosis of the oesophagus,
   (b) the swallowing of strong caustic material; with resulting scar,
   (c) irradiation or radiotherapy for carcinoma of lung or oesophagus etc.
2. Congentital—In the rare case of the true congenital stricture, small dilators may be used and are less likely to cause further damage and scarring than the conventional method of dilatation.
3. The strictures resulting from reflux oesophagitis—associated with an incompetent cardio-oesophageal junction or hiatus hernia. Following an operation to

prevent the reflux of acid, either by cure of the hernia or by vagatomy and drainage of the stomach, slow dilatation of the stricture may become feasible using this method.

2. Oesophageal varices.

To control bleeding oesophageal varices, as an emergency procedure in place of the conventional Sengstaken tube where this is indicated.

The dilator, by a constant pressure outwards (using the correct size and resilience of dilator) can produce the same effect as the Sengstaken tube without the disadvantages. These are:—

a. a tube all the way down the mouth, pharynx and oesophagus,
b. danger of inhalation pneumonia from inability to swallow saliva,
c. obstruction to vomiting,
d. the difficulties of feeding through the narrow lumen of the Sengstaken tube,
e. the fact that it has to be constantly watched with regard to pressure and deflated every six hours.

Using the dilator, the oesophageal varices can be compressed to secure haemostasis, at the same time allowing a wide lumen to permit the patient to swallow or vomit as the case may be; or the passage of tubes to wash out the stomach.

The dilator, providing it is correctly tensioned and of the correct size could be left in situ safely for longer periods—possibly up to a week in the acute phase—to control the bleeding while preparing the patient for a later, more definite procedure. In this case, alkalies are used to prevent reflex oesophagitis.

Employing the same principle as for the oesophagus, the above described dilators may also be used as:—

Urethral dilators
Common Bile Duct and Hepatic Duct Dilators
Wound Dilators
Anal Dilators
Vaginal Dilators.

Any orifice, or hollow organ which is scarred and physiologically narrowed may be dilated by this mechanism, which offers:—

a. minimal damage to epithelial lining
b. continuous slow stretching over a long period to avoid the traumatic effects of sudden stretching, with minimal formation of scar tissue. Thus early recurrent stricture is minimised.

Further, the dilators could be used for holding grafts, or hollow organs and blood vessels etc. while suturing; equipped with spikes 16 (Figure 4), it could hold the organ from within and thus save suturing in certain cases.

Also instrument 10 with remote control may be employed in place of the conventional bougies for momentary dilatation.

Further, if the instrument 10 is provided with a plurality of controls 11 circumferentially spaced, the distal end of the dilator can be angled to look around corners in any direction; fibre optics can be combined in such an instrument.

WHAT WE CLAIM IS:—

1. A surgical dilator comprising a hollow tubular member, the wall of which is provided by a tubular metal core of lattice form and a continuous layer of a resilient material, the elements making up the lattice defining diamond shapes in the unstressed condition of the dilator, the major diagonal dimension of each of which shape being in the direction of the longitudinal axis of the wall and the included acute angle of each shape in the unstressed condition of the dilator being between 45° and 60°, the dilator being such that when the dilator is subjected to an axial tensile force, the wall will be caused to contract diametrically and extend axially and will return substantially to its normal shape of its own accord when the force is removed.

2. A surgical dilator according to claim 1, wherein the core is embedded in the layer.

3. A surgical dilator according to claims 1 and 2, wherein the core is formed from woven filament material.

4. A surgical dilator according to any one of the preceding claims, wherein the core is formed from plaited filament material.

5. A surgical dilator according to any one of claims 1 to 3, wherein the core is formed from filament material crimped together.

6. A surgical dilator according to any one of claims 1 to 3, wherein the core is formed from two helical springs, one disposed within the other and wound in the opposite direction.

7. A surgical dilator according to any one of claims 1 to 3, wherein the core is formed from hinged slats tensioned by springs to tend to expand the dilator diametrically.

8. A surgical dilator according to any one of the preceding claims, wherein an end of the tubular member is divergent shaped.

9. A surgical dilator according to any one of the preceding claims, wherein loops are provided at the ends of the tubular member to enable an axial tensioning force to be applied to said member.

10. A surgical dilator according to any one of claims 1 to 7, wherein the external surface of the tubular member is provided with spikes.

11. A surgical dilator according to any one of claims 1 to 9, and including a removable cover surrounding said tubular member and retaining it in its axially extended position.

12. A surgical dilator substantially as here-

in described with reference to, and as illustrated in, any one of Figures 1 to 4 and 7 of the accompanying drawings.

13. A surgical instrument comprising an oesophagoscope, a surgical dilator according to any one of claims 1 to 7 or 12, secured to the distal end of the oesophagoscope, and manual control means for axially extending said dilator.

14. A surgical instrument in combination with a surgical dilator substantially as herein described with reference to, and as illustrated in, Figure 6 of the accompanying drawings.

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1205743 COMPLETE SPECIFICATION

2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1

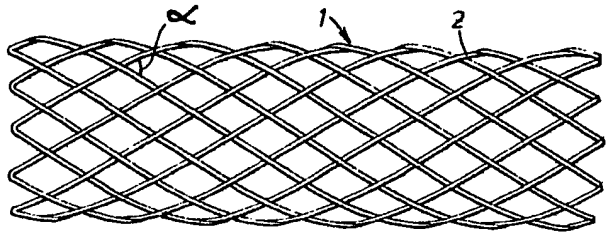


FIG. 1.

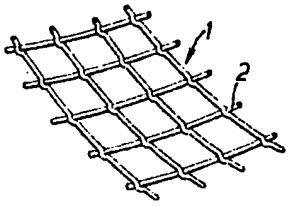


FIG. 2.

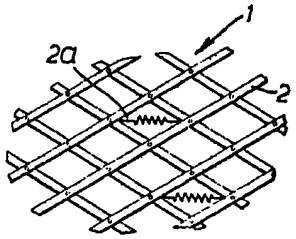


FIG. 3.

1205743 COMPLETE SPECIFICATION
2 SHEETS This drawing is a reproduction of the Original on a reduced scale
Sheet 2

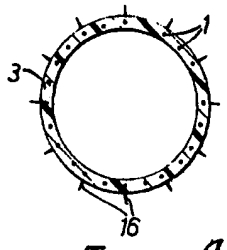


FIG. 4

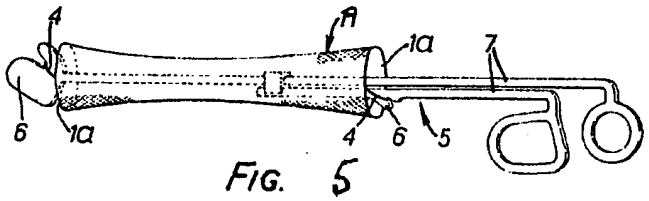


FIG. 5

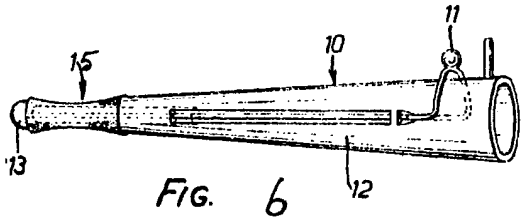


FIG. 6

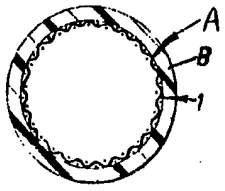


FIG. 7